IN THE

Supreme Court of the United States

OCTOBER TERM, 1947.

No. 121

UNITED STATES OF AMERICA,

Petitioner,

versus

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY,

Respondent.

On Writ of Certiorari to the Circuit Court of Appeals for the Fifth Circuit.

BRIEF FOR THE RESPONDENT.

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STATEMENT OF THE CASE.

The respondent Sullivan, a local retail merchant in Columbus, Georgia, in the month of December, 1944, made two (2) over-the-counter retail sales, in his drug store, of twelve (12) sulfathiazole tablets each, which were

not labeled as provided by the Federal Food, Drug and Cosmetic Act. He was convicted in the District Court for having violated Sec. 301 (k) of the Act (67 Fed. Supp. 192) and the Court of Appeals reversed this judgment with direction to acquit (161 F. 2nd 629).

The two (2) over-the-counter retail sales were made to different federal food and drug inspectors. One of the retail sales involved was made on December 13, 1944 (R. 4), and the other on December 14, 1944 (R. 6). Immediately preceding each retail sale the tablets were removed from a bottle on the shelf of respondent's drug store, and placed in a pill box labeled only "Sulfathiazole". At the time of said sales the bottle from which the tablets were removed was labeled in accordance with the Act. This bottle, so labeled, originally contained one thousand (1,000) tablets, at least nine (9) months before said sales, at some time between November 23, 1943 and March 15, 1944, had been shipped in interstate commerce from North Chicago, Illinois, to Abbott Laboratories in Atlanta, Georgia, and thereafter, on or about September 29, 1944, had been sold and delivered by Abbott in Atlanta, Georgia, to the respondent. This bottle was taken in charge by the inspectors after said retail sales, and its labeling up to the time of said retail sales had not been altered, mutilated, obliterated, destroyed or removed. It will be noted that the bottle remained with the importer in Atlanta, Georgia, at least a little over six (6) months before it was sold and shipped intrastate to the retailer at Columbus, Georgia; that it was kept on the shelf of the retailer in his drug store over two (2) months

before the sales were made; and, that at least nine (9) months elapsed after the interstate commerce was completed in Atlanta, Georgia, before the retail sales were made in Columbus, Georgia.

The information charged that respondent, by reason of the removal of said tablets from said bottle and the sale and delivery of them in a pill box, labeled as aforesaid, had violated Sec. 301 (k) of the Act, in that the labeling on the pill box did not contain adequate directions for use or adequate warning against use as provided in Sec. 502 (f) (1) and (2) of the Act.

The respondent made a motion to dismiss the information on the grounds that no offense was alleged; that respondent's acts were in intrastate commerce and were beyond the power of Congress to regulate, control or punish; that properly construed, the Act only applies to misbranding in interstate commerce, and if construed as applying to the acts of respondent, is unconstitutional. The trial court overruled respondent's motion to dismiss, and after the conclusion of the evidence upon the trial, which was before the Court without a jury, respondent made a motion for a judgment of acquittal upon the evidence (R. 47), which motion was overruled by the Court. Thereupon the Court entered a judgment of conviction, and then respondent filed his appeal.

QUESTIONS PRESENTED.

1. Is it the purpose and intention of the Federal Food, Drug and Cosmetic Act to regulate the intrastate retail sale of food and drugs and to regulate the labeling of foods and drugs when sold at retail in intrastate commerce?

2. Is Sec. 301 (k) of the Act, as applied to the acts of respondent, too vague, indefinite and uncertain to be enforceable?

3. If the Act, properly construed, applies to the acts of respondent, is it unconstitutional and in violation of the Tenth Amendment to the Constitution of the United States?

SUMMARY OF ARGUMENT.

1. The general purpose of the Act is declared in its title: "An Act to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices and cosmetics, and for other purposes." The Act does not intend to interfere with State regulation of selling at retail. The Act intends to respect the recognized line of distinction betdeen domestic and interstate commerce. It naturally would, as the distinction is constitutional. The Act seeks to keep interstate channels free of adulterated and misbranded articles to the end that the public health and safety might be advanced. It seeks to aid the States in making more effective their health

regulations, enacted in the exercise of the police power reserved to the States, so that the health and welfare of the citizens of the various States may be protected. There is no indication of any intention to regulate intrastate commerce because of any burdensome affect on interstate commerce. The talismanic expression "affecting interstate commerce" is not used. There are no findings or recitals in the Act that regulation of intrastate acts is necessary to effectuate the purpose of the Act. Nothing is more local than a retail sale. The Court should await a clearer mandate from Congress before adopting a construction of the statute which would be an inroad upon local conditions and local standards of such far-reaching import. The Court should so construe an act as to even avoid a serious doubt as to its constitutionality. The Court should not construe the act so as to give a federal agency control over myriads of local businesses heretofore traditionally left to local law, and make criminals of thousands of local grocers and druggists who sell intrastate from imported packages without mutilating the label.

2. Sec. 301 (k), and particularly that part of said section reading, "or the doing of any other act with respect to a food, drug, device or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded," as applied to the acts of respondent, is too vague, indefinite and uncertain to be enforceable as a criminal statute. A criminal statute should be strictly construed no matter what is its beneficient purpose. The

criminal action must be so explicitly and unambiguously defined that the ordinary man can know in advance how to avoid a criminal course of action. The prohibited acts should be defined with such care that only the foolhardy or vicious will be penalized. It is not permissible for the Court to search for an intention that the words themselves do not suggest. Sec. 301 (k) does not say that a person who buys in bulk any food or drug cannot sell in intrastate commerce at retail any part of such food or drug unless that part of such food or drug is labeled in accordance with the provisions of the Act, and that if such intrastate seller does not so label such food or drug that he will be guilty of a crime and be subject to a fine and imprisonment. In this case the interstate label was not changed or tampered with. The attempt here made is to extend Sec. 301 (k) so as to make criminal all retail sales made from the interstate package, though made clearly in intrastate commerce unless the labeling required by the Act is placed on the retail package. We insist that no grocer or druggist thus breaking an interstate package for a retail sale has understood that this was necessary. The Act has been in force since 1938, and yet we have been unable to find, and the government has not cited, a single reported case where the Food and Drug Administration has sought to prosecute a retail seller under the facts here involved.

3. If the Act is construed as applying to the acts of respondent, then the Act is unconstitutional and in violation of the Tenth Amendment to the Constitution of the United States, for it is a direct regulation for police

purposes of what is plainly intrastate commerce, which is the peculiar province of the State.

The authority of Congress and the scope of its power to regulate intrastate acts must be considered in the light of our dual system of government, and may not be extended so far as to embrace effects upon interstate commerce so indirect and remote, that to embrace them would effectually obliterate the distinction between what is national and what is local and create a completely centralized government. Such power cannot destroy the distinction which the commerce clause itself established between commerce among the several states and the internal concerns of a State. Congress has no power to substitute its will for that of the State in local matters, even though it may believe that the State, in its exercise of the police powers reserved to it, is unable or unwilling to enact and enforce legislation for the protection and advancement of the health of its citizens. The retail sales here involved did not and could not directly or substantially affect interstate commerce, and did not prevent Congress from prohibiting the movement in interstate commerce of adulterated and misbranded foods and drugs, which the statute states is its purpose. Therefore the Act is unconstitutional and void if properly construed as applying to the retail sales made by respondent.

ARGUMENT.

1. The Federal Food, Drug and Cosmetic Act does not and is not intended to apply to retail sales in intrastate commerce, or to misbranding in intrastate commerce. Stretch the Act as you will, its purpose is stated in its caption to be: "To prohibit the movement in *interstate commerce** of adulterated and misbranded foods, drugs, devices and cosmetics, and for other purposes." The statute rests, of course, upon the power of Congress to regulate interstate commerce, just as did the 1906 Food and Drug Act. As stated by Mr. Justice Holmes in *Weigle vs. Curtice, 248 U. S. 285,* at page 288:

> "The Food and Drugs Act indicates its intention to respect the recognized line of distinction between domestic and interstate commerce too clearly to need argument or an examination of its language. It naturally would, as the distinction is constitutional . . . When objects of commerce get within the sphere of State legislation, the State may exercise its independent judgment . . . When they get within that sphere is determined by the old long-established criteria. The Food and Drugs Act does not interfere with State regulation of selling at retail."

In *Nigro vs. United States 276 U. S. 332,* where the defendant was prosecuted for violating the Anti-Narcotic Act in that he sold morphine not in pursuance of a written order of the buyer on a form issued in blank for that purpose by the Commissioner of Revenue, the Court said:

> "If it is a mere act for the purpose of regulating and restraining the purchase of the opiate and other

* The italics in this brief are added.

drugs, it is beyond the power of Congress and invalid. We must assume it is a taxing measure for otherwise it would be no law at all."

In *FTC vs. Bunte Brothers, 312 U. S. 349*, where the commission issued a cease and desist order against Bunte for selling break and take packages in intrastate commerce, which was alleged to be in violation of the Federal Trade Commission Act, the Supreme Court, speaking through Mr: Justice Frankfurter, said in part:

"The construction of Section 5 urged by the Commission would thus give a Federal agency control over myriads of local businesses in matters heretofore traditionally left to local custom or local law . . . An inroad upon local conditions and local standards of such far-reaching import as involved here ought to await a clearer mandate from Congress."

It will be noted that the Federal Food, Drug and Cosmetic Act, like the Federal Trade Commission Act, and unlike the National Labor Relations Act and many other acts of Congress, does not expressly undertake to regulate matters affecting interstate commerce. As said by the Court in the *Bunte* case:

"When in order to protect interstate commerce Congress has regulated activities, which, in isolation, are merely local, it has normally conveyed its purpose explicitly . . .

". . . to read 'unfair methods of competition in (interstate) commerce' as though it meant 'unfair methods of competition in any way affecting interstate commerce', requires, in view of all the relevant

considerations, much clearer manifestations of intention than Congress has furnished."

Again, as stated in *National Labor Relations Board vs. Jones, 301 U. S. 1:*

> "The authority of the Federal Government may not be pushed to such an extreme as to destroy the distinction which the commerce clause itself established between commerce among the several States and the internal concerns of a State . . . The cardinal principle of statutory construction is to save and not to destroy. We have repeatedly held that as between two possible constructions of a statute, by one of which it would be unconstitutional and by the other valid, our plain duty is to adopt that which will save the act. Even to avoid a serious doubt the rule is the same . . . The critical words of this statute prescribing the limits of the board's authority in dealing with labor practices are 'affecting commerce'. Undoubtedly the scope of this power must be considered in the light of our dual system of government and may not be extended so as to embrace effects upon interstate commerce so indirect and remote that to embrace them, in view of our complex society, would effectually obliterate the distinction between what is national and what is local and create a completely centralized government."

The Federal Food, Drug and Cosmetic Act, to the end that the public health and safety might be advanced, seeks to keep *interstate* channels free of adulterated and misbranded drugs.

U. S. vs. Walsh, 331 U. S. 432.

The Act is in aid of the several States in the exercise of their police power to protect the health of their citizens. It is not a usurpation of such power. There is no indication of any intention to regulate intrastate commerce because of any burdensome affect on interstate commerce. There are no findings or recitals in the Act that it is necessary to regulate intrastate retail sales in order to effectuate the purposes of the Act. There is no reported case that we have been able to find and none have been cited by the government where the Food and Drug Administration has sought to regulate retail sales in intrastate commerce. That the Act has been successfully administered since 1938 without attempting to regulate retail sales is a persuasive reason to believe that it is not necessary to regulate retail sales in order to effectuate the purposes of the Act.

The government contends that the purpose to regulate retail sales is expressed in Sec. 301 (k), and particularly in the words "or the doing of any other act with respect to a food, drug, device or cosmetic while such article is held for sale after shipment in interstate commerce," and further says that Sec. 301 (k) is a statutory embodiment of this Court's decision in *McDermott vs. Wisconsin, 228 U. S. 115.* In the *McDermott* case, at pages 132 and 133, it is said:

> "The label on the unsold article is, in the one case, the evidence of the shipper that he has complied with the Act of Congress, while in the other, by its misleading and false character, it furnishes the proof upon which the federal authorities depend to reach and punish *the shipper* and to condemn the goods.

If truly labeled within the meaning of the Act, his goods are immune from seizure by the federal government; if the label is false or misleading within the terms of the law, the goods may be seized and condemned. In other words, the label is the means of vindication, or the basis of punishment in determining the character of the interstate shipment dealt with by Congress. In this connection it might be noted that as a practical matter, at least, the first time the opportunity of inspection by the federal authorities arises in cases like the present is when the goods, after having been manufactured, put up in package form and boxes in one State, and having been transported in interstate commerce, arrive at their destination, are delivered to the consignee, unboxed, and placed by him upon the shelves of his store for sale."

And on page 134 of the same case, it is said:

"To require the removal or destruction before the goods are sold of the evidence which Congress has by the Food and Drug Act, as we shall see, provided may be examined to determine the compliance or noncompliance with the regulations of the Federal Law, is beyond the power of the State."

And, again, on pages 135 and 136, it is said:

"For, as we have said, keeping within the constitutional limitations of authority, Congress may determine for itself the character of the means necessary to make its purpose effectual in preventing the shipment in interstate commerce of articles of a harmful character, and to this end may provide the means of inspection, examination, and seizure necessary to enforce the prohibitions of the Act, and when Par. 2

> has been violated, the federal authority, in enforcing either Par. 2 or Par. 10, may follow the adulterated or misbranded article *at least to the shelf of the importer* . . . The opportunity for inspection en route may be very inadequate. The real opportunity of government inspection may only arise, when, as in the present case, the goods as packed have been removed from the outside box in which they were shipped and remain as the Act provides, 'unsold'."

If Sec. 301 (k) is an embodiment of the McDermott case, it means that no one—at least the importer—may destroy the evidence—that is, the label on the goods shipped interstate—for to do so would deprive the interstate shipper of his means of vindication that he had labeled the interstate shipment according to the Federal Law, or on the other hand, would deprive the government of the evidence necessary to punish the interstate shipper for having shipped misbranded goods in interstate commerce.

In Sec. Ten (10) of the Food and Drug Act of 1906 (21 U. S. Code, Sec. 14; Chap. 3915, Sec. 10, 34 Stat. 771-772) which was before the Court in the *McDermott* case, following language is used:

> "Any article of food, drug or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State . . . to another for sale, or having been transported, *remains unloaded, unsold, or in original unbroken* packages . . . shall be liable to be proceeded against . . . and seized for confiscation . . ."

In the above language the unsold article was subject to seizure if it was misbranded while in interstate commerce. The McDermott case only holds that Congress has the power to require the evidence—the interstate label—to be preserved. And Sec. 301 (k) only means that the evidence cannot be destroyed—that the label that was on the package shipped in interstate commerce cannot be altered, obliterated, removed or destroyed. This is an entirely different thing from saying that a retail dealer cannot break an interstate package and make retail sales in intrastate commerce therefrom without labeling the retail sales as provided by the Act. In the case at bar, respondent did not interfere with the interstate label on the bottle—such label remained intact on the bottle all the while the article was held for sale.

If it was the intention of Congress by this section of the Act to regulate retail sales and the branding of articles sold in intrastate commerce, why didn't the legislative draftsman say so in plain unmistakable language? If that was the intention of Congress, which we insist is not true, the words "or the doing of any other act with respect to a drug while said article is held for sale after shipment in interstate commerce," did not say so. In the quoted language the word "sale" is in the singular. The *McDermott* case says that the federal authority may follow the misbranded article to the shelf of the importer to obtain the evidence that misbranded goods have been shipped in interstate commerce. This language fairly implies that while the misbranded goods remained on the shelf of the importer the government had a fair and

sufficient opportunity to inspect and examine the interstate labels to see whether or not misbranded goods had been shipped in interstate commerce, and therefore, after the sale by the importer it was not necessary to require the preservation of the interstate label.

Respondent insists that Sec. 301 (k) does not apply to retail intrastate sales made from interstate bulk packages, regardless of whether the retailer is the importer of the interstate bulk package or not. However, the importer who alters the label of an interstate package violates Sec. 301 (k) whether he is a retailer or not; but, whether a retailer who is not the importer and who alters the interstate label violates Sec. 301 (k) is immaterial in this case, because respondent did nothing whatever to the label on the bottle that had been shipped in interstate commerce.

But the government says that unless the Act is construed as requiring all retail dealers to label their retail intrastate sales of food, drugs, cosmetics and devices in accordance with the provisions of the Act, the public health will not be protected. Why? Is it assumed that the several States are unable or unwilling to protect their people?

Respondent, therefore, respectfully submits that the Federal Food, Drug and Cosmetic Act, when properly construed, does not apply to the acts of respondent.

2. Sec. 301 (k) of the Act and particularly the following language, "or the doing of any other act with re-

spect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce, and results in such article being misbranded," as applied to the acts of respondent is too vague, indefinite and uncertain to be enforceable as a criminal statute, for it did not adequately inform respondent that if he made an over-the-counter retail sale in intrastate commerce of a drug, that at some time in the past had been shipped in interstate commerce, that then he would be a criminal if he did not label such retail sale as provided by the Act.

All that respondent did in this case was to make two (2) over-the-counter retail sales in intrastate commerce from a bulk container—a bottle that had previously been shipped in interstate commerce. These retail sales were not labeled as required by the Act. But the bulk container—the bottle—was so labeled from the time it was shipped in interstate commerce until after said retail sales were made. This bottle was purchased by respondent in intrastate commerce in Atlanta, Georgia, some six (6) to ten (10) months after it had been received in interstate commerce by Abbott Laboratories, the seller. Respondent did not destroy any evidence that the government might need to prove that the bottle was either properly or improperly branded when shipped in interstate commerce. Even if he had altered the label on the bottle, the government had had from six (6) to ten (10) months to examine and inspect the bottle in Atlanta, Georgia, after it had been received in interstate commerce and had been unpacked from the outside shipping container. If

the criminal provision applies here, it applies to all retail sales of drugs, foods, cosmetics and devices no matter how many intermediate intrastate sales have been made, and no matter how long after such foods, drugs, cosmetics and devices had been in interstate commerce, and no matter whether such foods, drugs, cosmetics and devices had been shipped in interstate commerce in bulk or in retail containers.

It is one of the most fundamental precepts of criminal law that a penal statute should be definite and certain. It should define its orbit with exactitude so that a citizen may be aware of the penalties attendant upon a certain course of conduct. Liberty is a precious attribute of our civilization and a criminal statute is the most extreme example of restraint that our government knows. Fine and imprisonment are harsh deterrents, and the prohibited acts should be defined with care so that only the foolhardy or vicious will be penalized.

As stated in *Vol. 50, American Jurisprudence,* at page 244:

> "In accordance with what is commonly known as the rule of *ejusdem generis* where in a statute general words follow a designation of particular subjects . . ., the meaning of the general words will ordinarily be presumed to be and construed as restricted by the particular designation and as including only things or persons of the same kind, class, character or nature as those specifically enumerated."

In *Kraus vs. United States, 327 U. S. 614*, where the defendant was convicted of violating the Maximum Price Regulation 269, and where the defendant had required buyers to purchase chicken feet or chicken skin at a specified price as a condition of the sale of the poultry and it was charged that this conduct of the defendant was in violation of Section 1429-5 of the regulation, which provides that the regulation "shall not be evaded whether by direct or indirect methods, in connection with any offer, solicitation, agreement, sale, delivery, purchase or receipt of, or relating to, the commodities prices of which are herein regulated, alone or in conjunction with any other commodity, . . ., the Court said:

> "In a very literal sense the liberties and fortunes of others may depend upon his definitions and specifications regarding evasion. Hence to these provisions must be applied the same strict rule of construction that is applied to statutes defining criminal action. In other words, the Administrator's provisions must be explicit and unambiguous in order to sustain a criminal prosecution; they must adequately inform those who are subject to their terms what conduct will be considered evasive so as to bring the criminal penalties of the act into operation. The dividing line between unlawful evasion and lawful action cannot be left to conjecture. The elements of evasive conduct should be so clearly expressed by the Administrator that the ordinary person can know in advance how to avoid an unlawful course of action."

> "In applying this strict rule of construction to the provisions adopted by the Administrator, Courts must take care not to construe so strictly as to defeat the obvious intention of the Administrator. Words used

by him to describe evasive action are to be given their natural and plain meaning . . . But patent omissions and uncertainties cannot be disregarded when dealing with a criminal prosecution. A prosecutor in framing an indictment, a court in interpreting the Administrator's regulations or a jury in judging guilt cannot supply that which the Administrator failed to do by express words or fair implication. Not even the Administrator's interpretations of his own regulations can cure an omission or add certainty and definiteness to otherwise vague language. The prohibited conduct must, for criminal purposes, be set forth with clarity in the regulations . . . Congress has warned the public to look to that source alone to discover what conduct is evasive and hence likely to create criminal liability.

"In the light of these principles we are unable to sustain this conviction of the petitioner . . . ."

In *United States vs. Resnick, 299 U. S. 207,* where the defendant was indicted on charges of selling for fruits and vegetables, two-quart metal hampers which were not of any standard size authorized by the statute and did not come within any tolerance established by the Secretary of Agriculture without having submitted dimension specifications to the Secretary of Agriculture, and where Section 1 of the Act prescribes nine (9) standard sizes and two-quart hampers are not one of them, and Section 4 commands that no manufacturer shall manufacture hampers unless the dimension specifications shall have been submitted to and approved by the Secretary of Agriculture, it was held that the sale of such two-quart hampers were not within the terms of Section 5 of the Act, which

forbade the manufacture and sale of containers that do not comply with the Act. There the Court said:

> "Statutes creating crimes are to be strictly construed in favor of the accused; they may not be held to extend to cases not covered by the words used. Before one may be punished it must appear that his case is plainly within the statute; there are no constructive offenses."

In *United States vs. Weitzel, 246 U. S. 533,* Page 543, it was said:

> "Statutes creating and defining crimes are not to be extended by intendment because the Court thinks the legislature should have made them more comprehensve."

In *United States vs. Harris, 177 U. S. 305,* Page 310, the Court quoted from *United States vs. Wiltberger, 5 Wheat 76,* as follows:

> "The rule that penal laws are to be construed strictly is perhaps not much less old than construction itself. It is founded on the tenderness of the law for the rights of individuals, and on the plain principle that the power of punishment is vested in the legislature and not in the judicial department . . . It would be dangerous indeed to carry the principle that a case which is within the reason or mischief of a statute is within its provisions so far as to punish a crime not enumerated in the statute because it is of equal atrocity or of a kindred character with those which are enumerated."

In *Fasulo vs. United States, 272 U. S. 620,* where the defendant wrote and mailed a letter containing threats

of murder or bodily harm for the purpose of obtaining money and was indicted for violating Section 216 of the Criminal Code and the words of the statute relied on were as follows:

> "Whoever, having devised . . . any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promise, . . . shall, for the purpose of executing such scheme . . . place, or cause to be placed, any letter, . . . in any post office, . . . to be sent or delivered . . . shall be punished."

It was held that the defendant could not be convicted of violating the statute because the use of mails to obtain money by threats of murder is not in furtherance of a scheme to defraud. There the Court said:

> "While for the ascertainment of the true meaning and intention of the words relied on regard is to be had to the evils that called forth the enactment and to the rule that the strict construction of penal statutes does not require the words to be so narrowed as to exclude cases that fairly may be said to be covered by them, it is not permissible for the Court to search for an intention that the words themselves do not suggest . . .
>
> "There are no constructive offenses; and before one can be punished, it must be shown that his case is plainly within the statute.
>
> "We recognize the value of the rule of construing statutes with reference to the evil they were designed to suppress as an important aid in ascertaining the meaning of language in them that is ambiguous and equally susceptible of conflicting constructions. But

this Court has repeatedly held that this rule does not apply to instances that are not embraced in the language employed in the statute, or implied from a fair interpretation of its contents, even though they may involve the same mischief which the statute was designed to suppress."

In *United States vs. Ury, 106 F. 2nd 28,* cited by the government, there was no vagueness in the statute under which the appellee was convicted. The Act plainly said that if anyone removed the marks, required by the Act to be placed on an imported article, he should be convicted. Appellee removed the mark, and in so doing he did what the Act expressly and definitely prohibited. But Sec. 301 (k) does not say that if any person sells at retail in intrastate commerce any food, drug, device or cosmetic which previously had been shipped in bulk in interstate commerce, then such retailer shall be convicted if he does not label such retail sales as provided by the Act.

We earnestly insist that even if Congress had the constitutional power to regulate such isolated retail sales as are here involved, and even if Congress intended to regulate such sales and intended that any retail sale in intrastate commerce of any food, drug or cosmetic that was not labeled as the Act provided would be a crime and punishable by fine and imprisonment, Section 331 (k) of Title 21 of the United States Code is too indefinite as applied to the acts of respondent to be enforceable as a criminal statute. It does not adequately inform respondent that such sales and such labeling in interstate commerce is a crime.

3. If the Federal Food, Drug and Cosmetic Act is properly construed as applying to the acts of respondent, then the Act is unconstitutional and void in that it is in violation of the Tenth Amendment to the Constitution of the United States, and an invasion of the police powers reserved to the several states.

Respondent recognizes that under the commerce clause the Congress has power to regulate intrastate acts when such acts directly and substantially affect interstate commerce, or effectually defeat the particular regulation of interstate commerce in question. So, therefore, the question here is whether the regulation of the labeling of retail sales in intrastate commerce is necessary in order for Congress to prevent the movement in interstate commerce of misbranded foods, drugs, devices or cosmetics.

The commerce clause cannot be construed to reach all intrastate acts which might have an indirect effect upon interstate commerce, for to do so would destroy the distinction between domestic and interstate commerce, which the commerce clause itself has established, and the authority of the State over its domestic concerns would exist only by sufferance of the federal government, and there would be virtually no limit to the federal power and we would have a completely centralized government.

In *Schechter Poultry Corporation vs. United States*, 295 *U. S. 495*, this Court held the sale of sick chickens in intrastate commerce after they had been shipped in interstate commerce, could not have any direct and substantial affect upon such interstate commerce, and that the National Recovery Act, in so far as it sought to regulate

such retail sales, was unconstitutional and void. In the National Recovery Act, as well as in many other Acts, the Congress expressly attempted to regulate transactions affecting commerce, while there is no such language in the Federal Food, Drug and Cosmetic Act.

This case differs from the *United States vs. Darby, 312 U. S. 100,* where it was held the Congress had the power under the commerce clause to prohibit the shipment in interstate commerce of goods produced in violation of the Fair Labor Standards Act. The Darby case is more like *United States vs. Walsh, 331 U. S. 432,* where it was held that Congress had the right under the Federal Food, Drug and Cosmetic Act to punish the giving of a false guaranty by a seller selling misbranded or adulterated drugs to a purchaser regularly engaged in selling such drugs in interstate commerce where it was not shown that the particular misbranded or adulterated drugs had been shipped in interstate commerce by the purchaser.

The case at bar is distinguishable from *Wrightwood Dairy Company vs. United States, 315 U. S. 110,* where it was held that Congress, under the commerce clause, had the power to regulate the intrastate sale of milk in the Chicago Marketing Area, where it was necessary to regulate the price of such intrastate milk in order to make effective its regulation of the price of milk moving interstate into such area.

Also, in the case of *Wickard vs. Filburn, 317 U. S. 111,* it was likewise held that Congress, under the Agricultural Adjustment Act of 1938, in order to regulate the

national supply of wheat, had the right to regulate the production and disposition of Filburn's wheat, even though he was not engaged in interstate commerce.

In both of the Acts construed in the Wrightwood and Filburn cases, there were expressed findings and recitals in the Acts themselves that it was necessary to accomplish the purpose of the legislation to regulate intrastate acts affecting commerce.

In the opinion in the *Wrightwood* case this Court pointed out at page 124 that in the Schechter case "the defendants were not charged with injury to interstate commerce, or interference with persons engaged in that commerce, and that the acts charged had no different relation to or effect upon interstate commerce than like acts in any other local business which handles commodities brought into the State." This quotation respondent submits applies to the case at bar.

In *Federal Trade Commission vs. Bunte Brothers, 312 U. S. 349*, this Court, at page 353, said:

> "Translation of an implication drawn from the special aspects of one statute to a totally different statute is treacherous business. The Interstate Commerce Act and the Federal Trade Commsision Act are widely disparate in their historic setting, in the enterprises which they affect, in the range of control they exercise, and in the relation of these controls to the functioning of the federal system."

There is a wide difference between the regulation of the price and volume of production of agricultural prod-

ucts such as wheat and milk, and the regulation of food and drugs shipped in interstate commerce. If the purpose of the regulation is to regulate the price of interstate milk, there is an actual necessity to regulate the price of intrastate milk which competes with it. If the purpose of the regulation is to control the total supply of wheat in the United States, of necessity the production and disposition of wheat locally grown must be regulated. But it is not necessary for Congress to regulate the retail intrastate sale of food and drugs in order to prohibit the movement in interstate commerce of adulterated and misbranded drugs. Nor would the regulation of the interstate retail sale of food and drugs have any effect upon the efficiency of regulation of the interstate shipment of food and drugs.

In *Cloverleaf Butter Co. vs. Patterson, 315 U. S. 148,* this Court held that the State of Alabama could not seize and condemn unwholesome packing stock butter owned by a manufacturer engaged in renovating butter for sale in interstate commerce, because such State action was inconsistent with the federal regulations under the applicable federal statute. If the Federal Food, Drug and Cosmetic Act is construed as regulating retail intrastate sales, and is held constitutional, then the State regulation of such sales will be rendered invalid and unenforceable under the Cloverleaf decision and the result will be to deny to the several States the power to protect the health of their citizens. Surely the federal power should not be pushed to such an extent. In the opinion in the Cloverleaf case, in discussing the federal act there in question, the Court, at Page 168, said:

"It left the States free to act on the packing stock supplies prior to the time of their delivery to the manufacturer, and to regulate sales of the finished product within their borders."

Since the regulation of intrastate sales of food and drugs is not necessary to the accomplishment of the purpose, and can have no effect upon the prohibiting of the movement in interstate commerce of adulterated food and drugs, Congress has no constitutional power to regulate such intrastate sales, and if it attempted to do so, such regulation is invalid.

CONCLUSION.

We respectfully submit that the judgment of the Court of Appeals should be affirmed because Sec. 301 (k) of the Act is too indefinite to be enforceable as a criminal statute; the Act should be construed as not applying to the intrastate retail sales; and, if construed as applying to such retail sales, it is unconstiutional and void.

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This is to certify that copies of this brief have been served on opposing counsel on this the .... day of November, 1947.

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SUPREME COURT OF THE UNITED STATES.

No. 121.—October Term, 1947.

The United States of America, v. Jordan James Sullivan, Trading as Sullivan's Pharmacy.	On Writ of Certiorari to the United States Circuit Court of Appeals for the Fifth Circuit.

[January 19, 1948.]

Mr. Justice Black delivered the opinion of the Court.

Respondent, a retail druggist in Columbus, Georgia, was charged in two counts of an information with a violation of § 301 (k) of the Federal Food, Drug, and Cosmetics Act of 1938. That section prohibits "the doing of any . . . act with respect to, a . . . drug . . . if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."[1] Section 502 (f) of the Act declares a drug "to be misbranded . . . unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use . . . dangerous to health, or against unsafe dosage . . . as are necessary for the protection of users." The information charged specifically that the respondent had performed certain acts which resulted in sulfathiazole being "misbranded" while "held for sale after shipment in interstate commerce."

[1] "Sec. 301. The following acts and the causing thereof are hereby prohibited:

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded." 52 Stat. 1042, 21 U. S. C. § 331 (k).

The facts alleged were these: A laboratory had shipped in interstate commerce from Chicago, Illinois, to a consignee at Atlanta, Georgia, a number of bottles, each containing 1,000 sulfathiazole tablets. These bottles had labels affixed to them, which, as required by § 502 (f) (1) and (2) of the Act, set out adequate directions for the use of the tablets and adequate warnings to protect ultimate consumers from dangers incident to this use.[2] Respondent bought one of these properly labeled bottles of sulfathiazole tablets from the Atlanta consignee, transferred it to his Columbus, Georgia, drugstore, and there held the tablets for resale. On two separate occasions twelve tablets were removed from the properly labeled and branded bottle, placed in pill boxes, and sold to customers. These boxes were labeled "sulfathiazole." They did not contain the statutorily required adequate directions for use or warnings of danger.

Respondent's motion to dismiss the information was overruled, a jury was waived, evidence was heard, and respondent was convicted under both counts.

The Circuit Court of Appeals reversed. 161 F. 2d 629. The court thought that as a result of respondent's action the sulfathiazole became "misbranded" within the mean-

[2] The following inscription appeared on the bottle labels as a compliance with § 502 (f) (1) which requires directions as to use: "Caution.—To be used only by or on the prescription of a physician." This would appear to constitute adequate directions since it is required by regulation issued by the Administrator pursuant to authority of the Act. 21 C. F. R. Cum. Supp. § 2.106 (b) (3). The following appeared on the label of the bottles as a compliance with § 502 (f) (2) which requires warnings of danger: "Warning.—In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request."

ing of the Federal Act, and that in its "broadest possible sense" the Act's language "may include what happened." However, it was also of the opinion that the Act ought not to be taken so broadly "but held to apply only to the holding for the first sale by the importer after interstate shipment." Thus the Circuit Court of Appeals interpreted the statutory language of § 301 (k) "while such article is held for sale after shipment in interstate commerce" as though Congress had said "while such article is held for sale by a person who had himself received it by way of a shipment in interstate commerce." We granted certiorari to review this important question concerning the Act's coverage.

First. The narrow construction given § 301 (k) rested not so much upon its language as upon the Circuit Court's view of the consequences that might result from the broader interpretation urged by the Government. The court pointed out that the retail sales here involved were made in Columbus nine months after this sulfathiazole had been shipped from Chicago to Atlanta. It was impressed by the fact that, if the statutory language "while such article is held for sale after shipment in interstate commerce" should be given its literal meaning, the criminal provisions relied on would "apply to all intrastate sales of imported drugs after any number of intermediate sales within the State and after any lapse of time; and not only to such sales of drugs, but also to similar retail sales of food, devices and cosmetics, for all these are equally covered by these provisions of the Act." The court emphasized that such consequences would result in far-reaching inroads upon customary control by local authorities of traditionally local activities, and that a purpose to afford local retail purchasers federal protection from harmful foods, drugs and cosmetics should not be ascribed to Congress in the absence of an exceptionally clear mandate, citing *Federal Trade Commission* v. *Bunte*

Bros., 312 U. S. 349. Another reason of the court for refraining from construing the Act as applicable to articles misbranded while held for retail sale, even though the articles had previously been shipped in interstate commerce, was its opinion that such a construction would raise grave doubts as to the Act's constitutionality. In support of this position the court cited *Labor Board* v. *Jones & Laughlin Steel Corp.*, 301 U. S. 1, 30, and *Schechter Poultry Corp.* v. *United States*, 295 U. S. 495.

A restrictive interpretation should not be given a statute merely because Congress has chosen to depart from custom or because giving effect to the express language employed by Congress might require a court to face a constitutional question. And none of the foregoing cases, nor any other on which they relied, authorizes a court in interpreting a statute to depart from its clear meaning. When it is reasonably plain that Congress meant its Act to prohibit certain conduct, no one of the above references justifies a distortion of the congressional purpose, not even if the clearly correct purpose makes marked deviations from custom or leads inevitably to a holding of constitutional invalidity. Although criminal statutes must be so precise and unambiguous that the ordinary person can know how to avoid unlawful conduct, see *Kraus & Bros., Inc.* v. *United States*, 327 U. S. 614, 621–622, even in determining whether such statutes meet that test, they should be given their fair meaning in accord with the evident intent of Congress. *United States* v. *Raynor*, 302 U. S. 540, 552.

Second. Another consideration that moved the Circuit Court of Appeals to give the statute a narrow construction was its belief that the holding in this case with reference to misbranding of drugs by a retail druggist would necessarily apply also to "similar retail sales of food, devices and cosmetics, for all of these," the court said, "are equally covered by the same provisions of the Act." And in this

Court the effect of such a possible coverage of the Act is graphically magnified. We are told that its application to these local sales of sulfathiazole would logically require all retail grocers and beauty parlor operators to reproduce the bulk container labels on each individual item when it is taken from the container to sell to a purchaser. It is even prophesied that, if § 301 (k) is given the interpretation urged by the Government, it will later be applied so as to require retail merchants to label sticks of candy and sardines when removed from their containers for sale.

The scope of the offense which Congress defined is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its different misbranding provisions which relate to food, cosmetics, and the like. There will be opportunity enough to consider such contingencies should they ever arise. It may now be noted, however, that the Administrator of the Act is given rather broad discretion—broad enough undoubtedly to enable him to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of law. As an illustration of the Administrator's discretion, § 306 permits him to excuse minor violations with a warning if he believes that the public interest will thereby be adequately served. And the Administrator is given extensive authority under §§ 405, 503 and 603 to issue regulations exempting from the labeling requirements many articles that otherwise would fall within this portion of the Act. The provisions of § 405 with regard to food apparently are broad enough to permit the relaxation of some of the labeling requirements which might otherwise impose a burden on retailers out of proportion to their value to the consumer.

Third. When we seek the meaning of § 301 (k) from its language we find that the offense it creates and which is here charged requires the doing of some act with respect

to a drug (1) which results in its being misbranded, (2) while the article is held for sale "after shipment in interstate commerce." Respondent has not seriously contended that the "misbranded" portion of § 301 (k) is ambiguous. Section 502 (f), as has been seen, provides that a drug is misbranded unless the labeling contains adequate directions and adequate warnings. The labeling here did not contain the information which § 502 (f) requires. There is a suggestion here that, although alteration, mutilation, destruction, or obliteration of the bottle label would have been a "misbranding," transferring the pills to non-branded boxes would not have been, so long as the labeling on the empty bottle was not disturbed. Such an argument cannot be sustained. For the chief purpose of forbidding the destruction of the label is to keep it intact for the information and protection of the consumer. That purpose would be frustrated when the pills the consumer buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred from it to a non-labeled one. We find no ambiguity in the misbranding language of the Act.

Furthermore, it would require great ingenuity to discover ambiguity in the additional requirement of § 301 (k) that the misbranding occur "while such article is held for sale after shipment in interstate commerce." The words accurately describe respondent's conduct here. He held the drugs for sale after they had been shipped in interstate commerce from Chicago to Atlanta. It is true that respondent bought them nine months after the interstate shipment had been completed by their delivery to another consignee. But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had

received the articles at the end of the interstate shipment. Accordingly we find that the conduct of the respondent falls within the literal language of § 301 (k).

Fourth. Given the meaning that we have found the literal language of § 301 (k) to have, it is thoroughly consistent with the general aims and purposes of the Act. For the Act as a whole was designed primarily to protect consumers from dangerous products. This Court so recognized in *United States* v. *Dotterweich*, 320 U. S. 277, 282, after reviewing the House and Senate Committee Reports on the bill that became law. Its purpose was to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer. Section 301 (a) forbids the "introduction or delivery for introduction into interstate commerce" of misbranded or adulterated drugs; § 301 (b) forbids the misbranding or adulteration of drugs while "in interstate commerce"; and § 301 (c) prohibits the "receipt in interstate commerce" of any misbranded or adulterated drug, and "the delivery or proferred delivery thereof for pay or otherwise." But these three paragraphs alone would not supply protection all the way to the consumer. The words of paragraph (k) "while such article is held for sale after shipment in interstate commerce" apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer. Doubtless it was this purpose to insure federal protection until the very moment the articles passed into the hands of the consumer by way of an intrastate transaction that moved the House Committee on Interstate and Foreign Commerce to report on this section of the Act as follows: "In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k)

has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."[3] We hold that § 301 (k) prohibits the misbranding charged in the information.

Fifth. It is contended that the Act as we have construed it is beyond any authority granted Congress by the Constitution and that it invades the ~~power of~~ the States. A similar challenge was made against the Pure Food and Drug Act of 1906, 34 Stat. 768, and rejected, in *McDermott* v. *Wisconsin*, 228 U. S. 115. That Act did not contain § 301 (k), but it did prohibit misbranding and authorized seizure of misbranded articles after they were shipped from one State to another, so long as they remained "unsold." The authority of Congress to make this requirement was upheld as a proper exercise of its powers under the commerce clause. There are two variants between the circumstances of that case and this one. In the *McDermott* case the labels involved were on the original containers; here the labels are required to be put on other than the original containers—the boxes to which the tablets were transferred. Also, in the *McDermott* case the possessor of the labeled cans held for sale had himself received them by way of an interstate sale and shipment; here, while the petitioner had received the sulfathiazole by way of an intrastate sale and shipment, he bought it from a wholesaler who had received it as the direct consignee of an interstate shipment. These variants are not sufficient we think to detract from the applicability of the *McDermott* holding to the present decision. In both cases alike the question relates to the constitutional power of Congress under the commerce clause to regulate the branding of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce.

[3] H. Rep. 2139, 75th Cong., 3d Sess., 3.

The reasons given for the *McDermott* holding therefore are equally applicable and persuasive here. And many cases decided since the *McDermott* decision lend support to the validity of § 301 (k). See, *e. g.*, *United States* v. *Walsh*, 331 U. S. 432; *Wickard* v. *Filburn*, 317 U. S. 111; *United States* v. *Wrightwood Dairy Co.*, 315 U. S. 110; *United States* v. *Darby*, 312 U. S. 100; see *United States* v. *Olsen*, 161 F. 2d 669.

Reversed.

SUPREME COURT OF THE UNITED STATES

No. 121.—October Term, 1947.

The United States of America, v. Jordan James Sullivan, Trading as Sullivan's Pharmacy.	On Writ of Certiorari to the United States Circuit Court of Appeals for the Fifth Circuit.

[January 19, 1948.]

Mr. Justice Rutledge, concurring.

This case has been presented as if the Federal Food, Drug, and Cosmetics Act of 1938 had posed an inescapable dilemma. It is said that we must either (1) ignore Congress' obvious intention to protect ultimate consumers of drugs through labeling requirements literally and plainly made applicable to the sales in this case or (2) make criminal every corner grocer who takes a stick of candy from a properly labeled container and sells it to a child without wrapping it in a similar label.

The trouble-making factor is not found in the statute's provisions relating specifically to drugs. Those provisions taken by themselves are clear and unequivocal in the expressed purpose to protect the ultimate consumer by the labeling requirements. So is the legislative history. Standing alone, therefore, the drug provisions would cover this case without room for serious question.

However, those provisions do not stand entirely separate and independent in the Act's structure. In some respects, particularly in § 301 (k), they are interlaced with provisions affecting food and cosmetics. And from this fact is drawn the conclusion that this decision necessarily will control future decisions concerning those very different commodities.

If the statute as written required this, furnishing no substantial basis for differentiating such cases, the deci-

sion here would be more difficult than I conceive it to be. But I do not think the statute has laid the trap with which we are said to be faced. Only an oversimplified view of its terms and effects could produce that result.

The Act is long and complicated. Its numerous provisions treat the very different subjects of drugs, food and cosmetics alike in some respects, differently in others. The differences are as important as the similarities, and cannot be ignored. More is necessary for construction of the statute than looking merely to the terms of §§ 301 (k) and 502 (f).

It is true that § 301 (k) deals indiscriminately with food, drugs, devices and cosmetics, on the surface of its terms alone. Hence it is said that the transfer of sulfathiazole, a highly dangerous drug, from a bulk container to a small box for retail sale, could not be "any other act" unless a similar transfer of candies, usually harmless, also would be "any other act." From this hypothesis it is then concluded that the phrase must be interpreted with reference to the particularities which precede it, namely, "alteration, mutilation, destruction, obliteration or removal" of any part of the label, and must be limited by those particularities.

That construction almost, if not quite, removes "any other act" from the section. And by doing so it goes far to emasculate the section's effective enforcement, especially in relation to drugs. Any dealer holding drugs for sale after shipment in interstate commerce could avoid the statute's effect simply by leaving the label intact, removing the contents from the bulk container, and selling them, however deadly, in broken parcels without label or warning.

I do not think Congress meant the phrase to be so disastrously limited. For the "doing of any other act

with respect to a food, drug, device, or cosmetic" is prohibited by § 301 (k) only "if such act . . . results in such article being misbranded." And the statute provides, not a single common definition of misbranding for foods, drugs and cosmetics, but separate and differing sections on misbranded foods, misbranded drugs and devices, and misbranded cosmetics. §§ 403, 502, 602.

The term "misbranded" as used in § 301 (k) therefore is not one of uniform connotation. On the contrary, its meaning is variable in relation to the different commodities and the sections defining their misbranding. So also necessarily is the meaning of "any other act," which produces those misbranding consequences. Each of the three sections therefore must be taken into account in determining the meaning and intended scope of application for § 301 (k) in relation to the specific type of commodity involved in the particular sale, if Congress' will is not to be overridden by broadside generalization glossed upon the statute. As might have been expected, Congress did not lump food, drugs and cosmetics in one indiscriminate hopper for the purpose of applying § 301 (k), either in respect to misbranding or as to "any other act" which produces that consequence. Brief reference to the several misbranding sections incorporated by reference in § 301 (k) substantiates this conclusion.

The three sections contain some common provisions.[1] But the fact that each section is also different from the other two in important respects indicates that each broad subdivision of the Act presents different problems of interpretation. Neither the misbranded foods section nor the misbranded cosmetics section contains any provision directly comparable to § 502 (f), which the respondent here has violated. That section, however, is to be con-

[1] *E. g.*, §§ 403 (a), 502 (a) and 602 (a) are in identical language.

trasted with § 403 (k), one of the subsections dealing with misbranded foods. Comparison of the two provisions indicates that the doing of a particular act with respect to a drug may result in misbranding, whereas the same method of selling food would be proper.

Section 502 (f) provides that a drug shall be deemed to be misbranded:

> "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement."[2]

This provision, dealing with directions for use and warnings against improper use, in terms is designed "for the protection of users." To be effective, this protection requires regulation of the label which the container bears when the drug reaches the ultimate consumer.[3] The legislative history leaves no doubt that the draftsmen and sponsors realized the importance of having dangerous drugs properly labeled at the time of use, not just at the time of sale.[4] The intent to protect the public health is further emphasized by the limited scope of the proviso, which directs the Administrator to make exemptions only when compliance with clause (1) "is not necessary for the protection of the public health."

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[2] See S. Rep. No. 361, 74th Cong., 1st Sess. 19.

[3] See H. R. Rep. No. 2139, 75th Cong., 3d Sess. 8.

Section 403 (k), which contains the principal basis for "making every retail grocer a criminal," is very different. By its terms food is deemed to be misbranded:

> "If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream."

The section, in contrast to § 502 (f)'s comprehensive coverage of drugs, applies not to all foods shipped interstate, but only to the restricted classes containing artificial flavoring, or coloring, or chemical preservatives. The labeling requirement is much simpler. And the proviso confers a much broader power of exemption upon the Administrator than does the proviso of § 502 (f). Under the latter he is given no power to exempt on the ground that compliance is impracticable. He cannot weigh business convenience against protection of the public health. Only where he finds that labeling is not necessary to that protection is he authorized to create an exemption for drugs and devices. Health security is not only the first, it is the exclusive, criterion.

Under § 403 (k), however, in dealing with foods the Administrator can dispense with labels much more broadly. In terms the criterion for his action becomes "the extent that compliance . . . is impracticable" rather than, as under § 502 (f), "where any requirement of clause (1) [adequate directions for use] . . . is not necessary for the protection of the public health." Practical considerations affecting the burden of compliance by man-

ufacturers and retailers, irrelevant under § 502 (f), become controlling under § 403 (k). Thus under the statute's intent a much more rigid and invariable compliance with the labeling requirements for drugs is contemplated than for those with foods, apart from its greatly narrower coverage of the latter. And the difficulty of compliance with those requirements for such articles as candies explains the difference in the two provisos.[4]

These differences, and particularly the differences in the provisos, have a direct and an intended relation to the problem of enforcement. The labeling requirements for foods are given much narrower and more selective scope for application than those for drugs, a difference magnified by the conversely differing room allowed for exemptions. What is perhaps equally important, the provisos are relevant to enforcement beyond specific action taken by the Administrator to create exemptions.

His duty under both sections is cast in mandatory terms. Whether or not he can be forced by mandamus to act in certain situations, his failure to act in some would seem to be clearly in violation of his duty. Obviously there must be many more instances where compliance with the labeling requirements for foods will be "impracticable" than where compliance with the very different requirements

[4] "The proviso of this paragraph likewise requires the establishment of regulations exempting packages of assorted foods from the naming of ingredients or from their appearance in the order of predominance by weight where, under good manufacturing practice, label declaration of such information is impracticable. This provision will be particularly applicable, for example, to assorted confections, which under normal manufacturing practices may vary from package to package not only with respect to identity of ingredients but also in regard to the relative proportions of such ingredients as are common to all packages." S. Rep. No. 493, 73d Cong., 2d Sess. 12. The proviso discussed is in § 403 (i), not in § 403 (k); but the discussion brings out the sort of considerations which require exemption when compliance is impracticable.

for drugs will not be "necessary for the protection of the public health." That difference is obviously important for enforcement, particularly by criminal prosecution. I think it is one which courts are entitled to take into account when called upon to punish violations. The authors of the legislation recognized expressly that "technical, innocent violations . . . will frequently arise." S. Rep. No. 152, 75th Cong., 1st Sess. 4. In other words, there will be conduct which may be prohibited by the Act's literal wording, but which nevertheless should be immune to prosecution.

When that situation arises, as it often may with reference to foods, by virtue of the Administrator's failure to discharge his duty to create exemptions before the dealer's questioned action takes place, that failure in my judgment is a matter for the court's consideration in determining whether prosecution should proceed. Whenever it is made to appear that the violation is a "technical, innocent" one, an act for which the Administrator should have made exemption as required by § 403 (k), the prosecution should be stopped. This Court has not hesitated to direct retroactive administrative determination of private rights when that unusual course seemed to it the appropriate solution for their determination. *Addison* v. *Holly Hill Fruit Products*, 322 U. S. 607. If that is permissible in civil litigation, there is much greater reason for the analogous step of taking into account in a criminal prosecution an administrative officer's failure to act when the commanded action, if taken, would have made prosecution impossible.

It is clear therefore that the corner grocer occupies no such position of jeopardy under this legislation as the druggist, and that the meaning of § 301 (k) is not identical for the two, either as to what amounts to misbranding or as to what is "the doing of any . . . act" creating that result. The supposed dilemma is false.

Congress had power to impose the drug restrictions, they are clearly applicable to this case, the decision does not rule the corner grocer selling candy, and the judgment should be reversed. I therefore join in the Court's judgment and opinion to that effect.

SUPREME COURT OF THE UNITED STATES

No. 121.—October Term, 1947.

The United States of America, *v.* Jordan James Sullivan, Trading as Sullivan's Pharmacy.	On Writ of Certiorari to the United States Circuit Court of Appeals for the Fifth Circuit.

[January 19, 1948.]

Mr. Justice Frankfurter, dissenting.

If it takes nine pages to determine the scope of a statute, its meaning can hardly be so clear that he who runs may read, or that even he who reads may read. Generalities regarding the effect to be given to the "clear meaning" of a statute do not make the meaning of a particular statute "clear." The Court's opinion barely faces what, on the balance of considerations, seems to me to be the controlling difficulty in its rendering of § 301 (k) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1042; 21 U. S. C. § 331 (k). That section no doubt relates to articles "held for sale after shipment in interstate commerce and results in such article being misbranded." But an article is "misbranded" only if there is "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic." Here there was no "alteration, mutilation, destruction, oblieration, or removal" of any part of the label. The decisive question is whether taking a unit from a container and putting it in a bag, whether it be food, drug or cosmetic, is doing "any other act" in the context in which that phrase is used in the

setting of the Federal Food, Drug, and Cosmetic Act and particularly of § 301 (k).[1]

As bearing upon the appropriate answer to this question, it cannot be that a transfer from a jar, the bulk container, to a small paper bag, without transferring the label of the jar to the paper bag, is "any other act" when applied to a drug, but not "any other act" when applied to candies or cosmetics. Before we reach the possible discretion that may be exercised in prosecuting a certain conduct, it must be determined whether there is anything to prosecute. Therefore, it cannot be put off to some other day to determine whether "any other act" in § 301 (k) applies to the ordinary retail sale of candies or cosmetics in every drug store or grocery throughout the land, and so places every corner grocery and drug store under the hazard that the Administrator may report such conduct for prosecution. That question is now here. It is part of this very case, for the simple reason that the prohibited conduct of § 301 (k) applies with equal force, through the same phrase, to food, drugs and cosmetics insofar as they are required to be labeled. See §§ 403, 502, and 602 of the Act.

It is this inescapable conjunction of food, drugs and cosmetics in the prohibition of § 301 (k) that calls for a consideration of the phrase "or the doing of any other act," in the context of the rest of the sentence and with due regard for the important fact that the States are also deeply concerned with the protection of the health and welfare of their citizens on transactions peculiarly within local enforcing powers. So considered, "the doing of any other act" should be read with the meaning which radiates

[1] "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

to that loose phrase from the particularities that precede it, namely "alteration, mutilation, destruction, obliteration, or removal" of any part of the label. To disregard all these considerations and then find "a clear meaning" is to reach a sum by omitting figures to be added. There is nothing in the legislative history of the Act, including the excerpt from the Committee Report on which reliance is placed, to give the slightest basis for inferring that Congress contemplated what the Court now finds in the statute. The statute in its entirety was of course intended to protect the ultimate consumer. This is no more true in regard to the requirements pertaining to drugs than of those pertaining to food. As to the reach of the statute—the means by which its ultimate purpose is to be achieved—the legislative history sheds precisely the same light on the provisions pertaining to food as on the provisions pertaining to drugs. If differentiations are to be made in the enforcement of the Act and in the meaning which the ordinary person is to derive from the Act, such differentiations are interpolations of construction. They are not expressions by Congress.

In the light of this approach to the problem of construction presented by this Act, I would affirm the judgment below.

MR. JUSTICE REED and MR. JUSTICE JACKSON join in this dissent.